

AMENDMENTS TO THE CLAIMS

1.-50. (Cancelled)

51. (Currently amended) A method for detecting trophoblastic disease in a subject comprising:

(i) contacting a biological sample of the subject with at least two capture antibodies that specifically bind different epitopes of **invasive trophoblast antigen (ITA)**, **ITA** and hCG, and at least one detection antibody that binds an epitope of the ITA and hCG different from the epitopes bound by the capture antibodies, the at least one detection antibody being coupled to a label that is effective to produce a detectable signal in one assay;

(ii) detecting a signal produced by the label **when the detection antibody is bound to ITA**;

(iii) confirming that the subject is not pregnant; and

(iv) comparing the **total ITA and hCG** signal generated in the sample to the signal generated in a sample obtained from a normal, non-pregnant subject, wherein **the an** elevated signal in the sample relative to the sample from the normal, non-pregnant subject indicates trophoblastic disease in the subject.

52. (Previously presented) The method of claim 51, wherein the trophoblastic disease is a choriocarcinoma.

53. (Previously presented) The method of claim 51, wherein the trophoblastic disease is a hydatidiform mole.

54. (Previously presented) The method of claim 51, wherein the at least two capture antibodies are designated B152 and clone 827.

55. (Previously presented) The method of claim 51, wherein the at least two capture antibodies are designated B152 and clone 820.

56. (Previously presented) The method of claim 51, wherein the at least one detection antibody is designated B207.

57. (Previously presented) The method of claim 51, wherein the sample is selected from the group consisting of liquid samples and tissue samples.

58. (Previously presented) The method of claim 51, wherein the sample is a urine sample.

59. (Previously presented) The method of claim 51, wherein the sample is a serum sample.

60. (Previously presented) The method of claim 51, wherein the signal is a chemiluminescent signal.

61. (Previously presented) The method of claim 51, wherein the label is an acridinium ester.

62. (Previously presented) The method of claim 51, wherein the assay is automated.

63. (Currently amended) A method for detecting trophoblastic disease in a subject comprising:

(i) contacting a biological sample of the subject with at least two capture antibodies that specifically bind different epitopes of ITA and hCG, the two capture antibodies are designated B152 and clone 827, respectively, and at least one detection antibody, designated B207, that binds an epitope of the ITA and hCG different from the epitopes bound by the capture antibodies, the at least one detection antibody being coupled to a label that is effective to produce a detectable signal in one assay;

(ii) detecting a signal produced by the label when the detection antibody is bound to ITA;

(iii) confirming that the subject is not pregnant; and

(iv) comparing the total ITA and hCG signal generated in the sample to the signal generated in a sample obtained from a normal, non-pregnant subject, wherein **the an** elevated signal in the sample relative to the sample from the normal, non-pregnant subject indicates trophoblastic disease in the subject.

64. (Currently amended) A method for detecting trophoblastic disease in a subject comprising:

(i) contacting a biological sample of the subject with at least two capture antibodies that specifically bind different epitopes of ITA and hCG, the two capture antibodies are designated B152 and clone 820, respectively, and at least one detection antibody, designated B207, that binds an epitope of the ITA and hCG different from the epitopes bound by the capture antibodies, the at least one detection antibody being coupled to a label that is effective to produce a detectable signal in one assay;

(ii) detecting a signal produced by the label when the detection antibody is bound to ITA;

(iii) confirming that the subject is not pregnant; and

(iv) comparing the total ITA and hCG signal generated in the sample to the signal generated in a sample obtained from a normal, non-pregnant subject, wherein **the an** elevated signal in the sample relative to the sample from the normal, non-pregnant subject indicates trophoblastic disease in the subject.

65. (New) A method for detecting trophoblastic disease in a subject comprising:

(i) contacting a biological sample of the subject with at least two capture antibodies that specifically bind different epitopes of invasive trophoblast antigen (ITA), and at least one detection antibody that binds an epitope of the ITA different from the epitopes bound by the capture antibodies, the at least one detection antibody being coupled to a label that is effective to produce a detectable signal in one assay;

(ii) detecting a signal produced by the label when the detection antibody is bound to ITA;

(iii) confirming that the subject is not pregnant; and
(iv) comparing the signal generated in the sample to the signal generated in a sample obtained from a normal, non-pregnant subject, wherein an elevated signal in the sample relative to the sample from the normal, non-pregnant subject indicates trophoblastic disease in the subject.

66. (New) The method of claim 65, wherein the trophoblastic disease is a choriocarcinoma.

67. (New) The method of claim 65, wherein the trophoblastic disease is a hydatidiform mole.

68. (New) The method of claim 65, wherein the at least two capture antibodies are designated B152 and clone 827.

69. (New) The method of claim 65, wherein the at least two capture antibodies are designated B152 and clone 820.

70. (New) The method of claim 65, wherein the at least one detection antibody is designated B207.

71. (New) The method of claim 65, wherein the sample is selected from the group consisting of liquid samples and tissue samples.

72. (New) The method of claim 65, wherein the sample is a urine sample.

73. (New) The method of claim 65, wherein the sample is a serum sample.

74. (New) The method of claim 65, wherein the signal is a chemiluminescent signal.

75. (New) The method of claim 65, wherein the label is an acridinium ester.

76. (New) The method of claim 65, wherein the assay is automated.